## REMARKS

Claims 1, and 4-20 remain pending after entry of this amendment. Claims 2 and 3 were cancelled herein. Claims 1, 4, 5, 8-10, 12, 13, and 15-18 were amended herein. Favorable reconsideration is respectfully requested in light of the amendments and remarks submitted herein.

Claim 8 is objected to because it did not end in a period. Claim 8 has been amended to add a period at the end of the sentence. Applicant respectfully requests that this objection be withdrawn.

Claims 5, 8-10, 12-13, and 15-18 are rejected under 35 U.S.C. § 112, second paragraph. Applicant respectfully traverses this rejection.

Claim 3 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,414,036. Applicant respectfully traverses this rejection.

Claims 1 and 2 and 4-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 20-23 of U.S. Patent No. 6,414,036. Applicant respectfully traverses this rejection.

Claims 1, 2, 4, and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by the Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck). Applicant respectfully traverses this rejection.

Claims 1, 2, 19, and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Avery's Drug Treatment, 4th Edition, Chapter 31, pp. 1455-1509 (Avery). Applicant respectfully traverses this rejection.

Claims 1-2, 4, 8-9, 12, and 19-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ropapharm B.V., EP 0904780A1 (Ropapharm). Applicant respectfully traverses this rejection.

Claims 1-2, 4, 8, 9, 12, and 14-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ropapharm. Applicant respectfully traverses this rejection.

Claims 1, 2, 4, and 10-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Merck and common knowledge in the art. Applicant respectfully traverses this rejection.

Claims 3 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ropapharm as applied to claims 1, 2, 4, 8, 9, 12, 19, and 20 above and further in view of

Remington's Pharmaceutical Sciences, Fifteenth Edition, 1975, pp. 1405-1412 (Remington). Applicant respectfully traverses this rejection.

**Rejections under 35 U.S.C. § 112**

Claims 5, 8-10, 12-13, and 15-18 are rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner asserts that the limitation "the Group I base" which is recited in claim 5 does not have sufficient antecedent basis. Claim 5 has been amended to replace "Group I base" with "Group I salt", for which there is proper antecedent basis.

The Examiner also asserts that claims 8-10, 12-13, and 15-18 are vague and indefinite because it is unclear what the percentages are based upon. Although Applicant respectfully asserts that one of skill in the art generally knows that weight percentages are based on the weight of the specific composition that is being recited, Applicant has amended claims 8-10, 12, 13, and 15-18 respectively. Applicant therefore respectfully requests that this amendment be withdrawn.

**Double-Patenting Rejections**

Claim 3 is rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,414,036 ("'036"). Although claim 3 has been cancelled, Applicant will address this rejection to the extent it may be applied to claim 1, because claim 1 essentially incorporated the limitations of claim 3.

Applicant respectfully asserts that this is not a proper rejection under statutory double patenting. In order to be a proper statutory double patenting rejection, the same invention has to be claimed twice. The "same invention" means **identical** subject matter. Claim 3 of the pending application and claim 1 of issued U.S. Patent No. 6,414,036 do not cover **identical** subject matter. One difference between amended claim 1 and claim 1 of '036 is that the instant claim 1 specifies that the pharmaceutically acceptable carrier is suitable for parenteral administration. Claim 1 of '036 does not include this element. Therefore, the subject matter of these two claims is not identical, because claim 1 of '036 arguably covers more and/or different subject matter. Based on the comments offered above, Applicant respectfully requests that this rejection be withdrawn.

Claims 1 and 2 and 4-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 20-23 of U.S. Patent No. 6,414,036. Although Applicant does not necessarily concede the correctness of this rejection, it will be remedied when the subject matter is otherwise allowable with the filing of a terminal disclaimer. Applicant also reserves the right to argue that this rejection is not proper.

**Rejections under 35 U.S.C. § 102**

Claims 1, 2, 4, and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by the Merck Index, An Encyclopedia of Chemicals, Drugs, and Biologicals, 12th Edition, 1996, page 9539 (Merck).

Claims 1, 2, 19, and 20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Avery's Drug Treatment, 4th Edition, Chapter 31, pp. 1455-1509 (Avery).

Claims 1-2, 4, 8-9, 12, and 19-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ropapharm B.V., EP 0904780A1 (Ropapharm

Although Applicant does not necessarily agree with these rejections, claim 1 has been amended to incorporate the additional elements of claim 3 (and intervening claim 2), which was not rejected. Therefore, Applicant respectfully asserts that claim 1 is no longer anticipated. Applicant therefore respectfully requests that these rejections be withdrawn.

**Rejections under 35 U.S.C. § 103**

Claims 1-2, 4, 8, 9, 12, and 14-20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ropapharm.

Claims 1, 2, 4, and 10-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Merck and common knowledge in the art.

Although Applicant does not necessarily agree with these rejections, claim 1 has been amended to incorporate the additional elements of claim 3 (and intervening claim 2), which was not rejected. Therefore, Applicant respectfully asserts that claim 1 is no longer obvious in light of these references. Applicant therefore respectfully requests that these rejections be withdrawn.

Applicant notes that the Office Action did not specifically state that claims 3 and 13 were rejected under this rejection, but based on the text of the rejection, Applicant assumes that claims 3 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ropapharm as applied

to claims 1, 2, 4, 8, 9, 12, 19, and 20 above and further in view of Remington's Pharmaceutical Sciences, Fifteenth Edition, 1975, pp. 1405-1412 (Remington). Although claim 3 has been cancelled, Applicant will address this rejection to the extent it may be applied to claim 1, because claim 1 essentially incorporated the elements of claim 3.

The Examiner characterizes the disclosure of Ropapharm and notes that it does not teach the sodium chloride of claim 13, which qualifies as a Group I salt, as claimed in claim 3. The Examiner then asserts that Remington's teaches that solutions of sodium chloride or dextrose are used to adjust hypotonic intravenous solutions to isotonicity, and therefore it would have been obvious to one of ordinary skill in the art to add sodium chloride to Applicant's composition.

In order to establish *prima facie* obviousness, three basic criteria must be met, namely: (1) there must be some suggestion or motivation to combine the references or modify the reference teaching; (2) there must be a reasonable expectation of success; and (3) the reference or references when combined must teach or suggest each claim limitation. Applicant submits that the Office Action failed to state a *prima facie* case of obviousness, and therefore the burden has not properly shifted to Applicant to present evidence of nonobviousness.

Applicant respectfully asserts that the references, when combined to not teach or suggest each claim element. Original claim 3, now claim 1 includes the element that the organic phenolic compound is reacted with at least one Group I salt. Remington teaches that the sodium chloride or dextrose is added in order to adjust the isotonicity of the injectable formulation. However, Applicant reacts the Group I salt with the organic phenolic compound. These are two different processes that create two different products.

Applicant's claim 1 comprises an organic phenolic compound reacted with a Group I salt. "Reacting" is defined in the specification, at least at page 10, lines 4 through 9. The specification states that "the term 'reacting' refers to a process in which the organic phenolic compound is chemically modified (as compared to the formation of a solution)."

The reaction that occurs causes the alcohol moiety of the organic phenolic compound to be deprotonated, resulting in an aryl oxide anion of the organic phenolic compound, which then associates with the Group I cation from the Group I salt. In contrast, forming a solution is simply a process of homogeneously distributing the components throughout the volume of the solution.

The use of a solution of sodium chloride to modify the isotonicity of the formulation is simply the formation of a solution. A method of forming a solution would not necessarily, and would not be desired to, result in the compounds contained therein being chemically "reacted". Therefore, Applicant asserts that the combination of Ropapharm and Remington fail to teach all of the claim limitations, namely that the "organic phenolic compound is reacted with a Group I salt", and does therefore not render Applicant's invention obvious. Applicant therefore respectfully requests that this rejection be withdrawn.

**Conclusion**

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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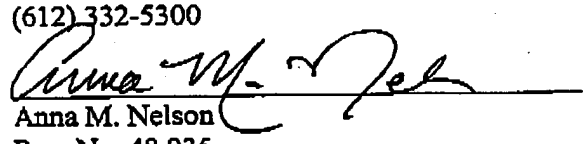

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